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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,088	03/22/2004	Mary R. Flack	225011	1687

45733 7590 10/03/2005

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EXAMINER	
WEDDINGTON, KEVIN E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/806,088	FLACK ET AL.	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3-7,10-16,18-23 and 26-30* is/are allowed.

6)☒ Claim(s) *1,2,8,9,17,18,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-20-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SD

Claims 1-30 are presented for examination.

Applicants' response and declaration filed May 12, 2005; and the amendment filed June 27, 2005 have been received and entered.

Accordingly, the rejections made under 35 USC 102 and 103 as set forth in the previous Office action dated December 21, 2004 at pages 2-5 are hereby withdrawn so that a new rejection can be made.

Reissue Applications

Allowable Subject Matter

Claims 3-7, 10-16, 18-23 and 26-30 are allowable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yerukhimov, "Treatment of Bladder Tumors with Gossypol and Ionol in Combination with Surgical Intervention", Voprosy Onkologii, (1966), Vol. 12(2), pp. 29-34, (BX of PTO-1449 dated December 2004).

Yerukhimov teaches the use of racemic gossypol to treat bladder cancer (see page 32 for the summarized in Table 4 and Table 5). Note the racemic gossypol contains both the (+) and (-) enantiomers, therefore, the (-) enantiomer was

administered to produce the same anti-cancer effects. Clearly, the cited reference anticipates the applicants' instant invention, treat a cancer with (-)-gossypol; therefore, the instant invention is unpatentable.

Claims 1and 8 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 8, 9, 17, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yerukhimov, "Treatment of Bladder Tumors with Gossypol and Ionol in Combination with Surgical Intervention", Voprosy Onkologii, (1966), Vol. 12(2), pp. 29-34, (BX of PTO-1449 dated December 2004), in view of V. Band et al.,

"Cytocidal Effects of Gossypol and Its Optical Isomers on Reproductive Cancer Cell Lines", Gynecologic Oncologists, (1986), 23(2), p. 261, (AH of PTO-1449) further in view of Band et al., "Antiproliferative Effect of Gossypol and Its Optical Isomers on Human Reproductive Cancer Cell Lines", Gynecologic Oncology, (1989), 32, pps-273-277, (AG of PTO-1449).

Yerukhimov teaches the use of racemic gossypol to treat bladder cancer as discussed above supra.

V. Band et al. teach cell lines (in vitro) gossypol has cytocidal effect on ovarian, testicular and gestational tumor cells.

Based on the success of Yerukhimov and the teaching of V. Band et al., one of ordinary skill in the art would have been motivated to treat ovarian, testicular, and gestational types of cancer by administering gossypol as taught in the Yerukhimov reference. Thus the claimed invention is a prima facie obvious to make and use at the time it was made.

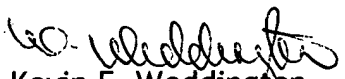
In addition given the combined teaching of Yerukhimov and V. Band et al. in view of Band et al, it would have been obvious to one of ordinary skill in the art to have used (-) gossypol since Band et al. (AG) teach that the (-) enantiomer is the primary antiproliferative agent in the racemic mixture delivered in the Yerukhimov and V. Band et al. references.

Claims 2, 8, 9, 17, 24 and 25 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7: 30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
August 22, 2005